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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/547,532	04/12/2000	Dean F. Carson	014	5869

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02/26/2004

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

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DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/547,532

Applicant(s)

CARSON ET AL

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
4a) Of the above claim(s) 11-13 and 20-69 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-8, 10, 14-16, 18 and 19 is/are rejected.
7) ☒ Claim(s) 9 and 17 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1-6, 10, 14-16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Angelchik US 4,352,358. Angelchik discloses an anastomosis device comprising a conduit (the whole device is the conduit), a first securing element (13) and a second securing element (10). The conduit extends away from the vessel without passing through the target vessel. The applicant discloses the conduit as element 10. While it is not clear how the device actually comprises a conduit when the conduit appears to be the device itself, the Angelchik reference anticipates this type of limitation in a congruent manner.

Regarding claim 2, the applicant hasn't disclosed in the specification that the components are non-circular. To the examiner, the components appear in the drawings to be circular. As best understood, the Angelchik device has components with a non-circular periphery. The flat sides of the Angelchik components (10, 13) comprise the non-circular peripheries.

Regarding claim 3, the radius of curvatures of the Angelchik device's components are made with a given size. Since blood vessels are naturally occurring and vary greatly in size,

there will inherently be some blood vessels capable of use with the Angelchik device that have a radius of curvature that substantially matches radius of curvature of the Angelchik components.

Regarding claim 4, the conduit is a separate member coupled to the second securing component to form a continuous luminal surface substantially free of discontinuities.

Regarding claim 5, the Angelchik is made out of plastic, which is a vascular graft material.

Regarding claim 6, a T-shape configuration is formed by the junction of the conduit and second securing component. The first securing component has a complimentary T-shaped configuration capable of being received in the junction of the second securing configuration (I.E. by squeezing the components together.)

Regarding claim 10, the Angelchik device is capable of lying flat along an area between the blood source and target vessel.

Regarding claim 14, element 11 couples the securing elements together. The proximal end of the conduit can be used for establishing a fluid communication with a heart chamber.

Regarding claims 15 and 16, the second securing element of Angelchik is about 1.25 times the size of the first securing member.

Regarding claim 19, the first and second member secure the conduit and do so without penetrating the vessel wall.

2. Claims 1, 7, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Zegdi et al. (Zegdi) US 5,893,886. Regarding claim 1, Zegdi discloses an anastomosis device comprising a conduit (6), a first securing element (11) and a second securing element (8). The conduit

extends away from the vessel without passing through the target vessel. See the attached figure for the limitations of the conduit.

Regarding claim 7, element 9b in Zegdi et al. functions a conduit supporting device coupled to the second securing component for contacting tissue adjacent the target vessel to prevent the device from collapsing the target vessel.

Regarding claim 19, the first and second member secure the conduit and do so without penetrating the vessel wall.

3. Claims 1, 6, 8, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Yencho et al. (Yencho) US 6,206,913. Yencho discloses an anastomosis device comprising a conduit (21), a first securing element (16) and a second securing element (11). The conduit extends away from the vessel without passing through the target vessel.

Regarding claim 6, a T-shape configuration is formed by the junction of the conduit and second securing component. The first securing component has a complimentary T-shaped configuration capable of being received in the junction of the second securing configuration.

Regarding claim 8, elements 17 are the securing mechanism.

Regarding claim 18, the securing member (16) of the Yencho et al. patent functions as a radiopaque marker. A wire is inherently radiopaque.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angelchik 4352358 in view of Ramberg US 2962050 A. The conduit of Angelchik is described as a tubular elastic membrane. It is well known to add reinforcing members in the form of wires, braces, or weaves which can be incorporated into or surrounding the membrane which will alter the elasticity, ductility or strength of the membrane and thereby the conduit. Ramberg discloses a hose that uses a braid to strengthen the burst pressure of the hose. At the time of the invention it would have been obvious to one having ordinary skill in the art to add a strengthening element (such as the braid in Ramberg '050) to the Angelchik conduit to strengthen the conduit so the conduit better resists failure.

Allowable Subject Matter

5. Claims 9 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, while the snap-fit system as suggested by claim 9 is well-known in the art, none of the references cited uses a snap-fit (groove and projection) system to lock a first and second securing member together.

Regarding claim 17, the Zegdi reference does not have a vessel-supporting member that is separate from the second component that helps maintain the shape of the vessel. In the Yecho

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device, elements 17 do not aid in maintaining the vessel's shape. In Angelchik, no element is seen which helps maintain the shape of the vessel.

Conclusion

Status of claims: Claims 1-69 are pending. Claims 1-10 & 14-19 are elected and claims 11-13 & 20-69 are withdrawn from further consideration. Claims 1-8, 10, 14-16, and 18-19 are rejected. Claims 9 and 17 are objected to.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5342393 A	Method and device for vascular repair
US 6036705 A	Anastomosis connection system and method of use
US 5620461 A	Sealing device
US 5141516 A	Dissolvable anastomosis stent and method for using the same
US 6524322 B1	Anastomosis device
US 6660015 B1	Medical graft connector or plug structures


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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02/20/04



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